K031986

JUL 2 4 2003

510(k) SUMMARY

Submitted by:	ICS MEDICAL 125 Commerce Drive Schaumburg, IL 60173-5329
Telephone:	(847)-534-2150
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Contact Person:	Delmar F. Bloem, President
Date Summary Prepared:	June 26, 2003
Trade Name of Device:	ICS Medical CHARTR® EP with ASSR and CHARTR® OAE Systems
Common Name:	Auditory Evoked Potential System and Otoacoustic Emissions Analyzer System.
Classification Name:	Auditory Evoked Potential System and Audiometer
Substantial Equivalence:	The CHARTR® EP with ASSR CHARTR® OAE Systems Product is substantially equivalent to the CHARTR® EP and CHARTR OAE Systems which has a cleared 510(k): K002985.

Intended Use:

The CHARTR® EP with ASSR System is indicated for auditory evoked potential testing as an aid in detecting hearing loss and lesions in the auditory pathway.

The CHARTR® OAE is indicated for the determination of cochlear function in infants, children, and adults which provides information about hearing without subjective response from the individual being tested.

Scientific Principle:

ASSR (Auditory Steady-State Response) testing is based on the long-established principle that stimuli presented at fast rates evoke brain responses that overlap (so-called "steady-state" responses). The overlap results in a stable sinusoidal pattern in the patient's electroencephalogram (EEG). The pattern is detectable with computer algorithms, and is stable only in the EEG of patients whose auditory system responds to the stimulus.

With auditory stimuli, amplitude- and/or frequency-modulation of a sine wave (pure tone) results in a stimulus that is both relatively frequency-specific and capable of evoking a detectable steady-state response. Research studies have demonstrated that when several such stimuli are presented to a patient simultaneously, the response to each stimulus can be extracted from the (composite) EEG, and the results are comparable to those obtained when the stimuli are presented sequentially. This technique enables assessment of hearing at several frequencies at once.

Responses are detected through analysis of digital samples of the patient's EEG. The analysis consists of two stages: estimation and statistical detection. Estimation involves calculations performed on the EEG samples to produce periodic values for amplitude and/or phase of each response sought. Estimates for each response are passed to a statistical algorithm that calculates the confidence, in percent, that the estimates are consistent with a stable response to the corresponding stimulus. The software declares a response to be present when the confidence reaches a predetermined threshold (i.e. 95%). If the confidence does not reach this threshold within a predetermined amount of time (i.e. 5 minutes of testing), the software declares that no response could be found.

Electrical Safety:	Both Systems are designed to meet EN 60601-1 standard for Medical devices.
EMI Compatibility:	Both Systems are designed to meet EN 60601-1-2 standard.

Comparison Table for
CHARTR® EP vs. CHARTR® EP with ASSR

	CHARTR EP	CHARTR EP with ASSR
Stimulus	Click or tone burst	Modulated continuous pure tone
Transducers	Insert, bone	Insert, bone, speaker
Intensity	0-90 db HL	0-120 dB HL
Electrode montage	Low forehead, high forehead and both ears	Low forehead, high forehead and one ear
Patient state	Sleeping or resting quietly	Same
Interpretation	Audiologist subjectively identifies responses	Algorithm objectively identifies responses
Clinical purpose	Indicated for auditory evoked potential testing as an aid in detecting hearing loss and lesions in the auditory pathway	Same
Patient population	Adults, children, and infants.	Same
Hardware configuration	Audio board	Audio board with daughter board to provide multiple AM/FM modulated tones
Operating system	Win98	Same
Software – protocol with ASSR	No	Yes
Electrical Safety	Designed to comply with EN 60601-1 (UL2601)	Same
EMI Compatibility	Designed to comply with EN 60601-1-2	Same
Computer System	MCU-90 (IBM compatible tower) and Portable (TFT active matrix screen) computer	Same
Labeling	Identical for both units	Same
Operator Manual	Covers CHARTR EP version 2.0	Contains updates for EP versions 3.0 and 4.0

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 24 2003

ICS Medical
c/o Delmar F. Bloem, President
125 Commerce Drive
Schaumburg, IL 60173-5329

Re: K031986
Trade/Device Name: ICS MEDICAL CHARTR® EP WITH ASSR AND CHARTR® OAE SYSTEMS
Regulation Number: 21 CFR 874.1050
Regulation Name: Audiometer
Regulatory Class: II
Product Code: EWO
Dated: June 26, 2003
Received: June 27, 2003

Dear Mr. Bloem:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K031986

Device Name: ICS Medical CHARTR® EP with ASSR and CHARTR® OAE Systems

Indications For Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

James K. Kan, Ph.D.

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K031986

(Optional Format 3-10-98)